REMARKS / ARGUMENTS

In response to the office action of May 19, 2009, Applicant has amended the claims, which when considered with the following remarks, is deemed to place the present application in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

In the office action of May 19, 2009, claims 11-22 have been rejected under the written description requirement of 35 U.S.C. § 112, first paragraph. It is the position of the examiner that since the transitional phrase "consisting essentially of" does not appear in the originally filed disclosure and claims, such language is new matter. Solely for the purposes of advancing prosecution of this application, and not in any way acquiescing to the position of the examiner, claims 11 and 19 have been amended to recite "consisting of" rather than "consisting essentially of." Withdrawal of the rejection of claims 11-22 under the written description requirement of 35 U.S.C. § 112, first paragraph is therefore warranted.

Claims 11, 12, 14 and 16-22 have been rejected under 35 U.S.C.§ 102(e) as allegedly anticipated by Uomoto et al. (US 5,380,745). Uomoto et al. has been cited for teaching medicinal compositions comprising a practically water-insoluble compound. Uomoto is also relied upon for teaching that the medicinal compositions may comprise either one or more compounds selected from either or both nonionic surfactants and fats and oils including sorbitan fatty acid esters, polyoxyethylene sorbitan fatty acid esters and polyglycerol fatty acid esters as surfactants and soybean oil, rapeseed oil, castor oil and cotton seed oil.

In response to the rejection, claims 11 and 19 have been amended to recite a therapeutic agent selected from rapamycin, tacrolimus and mycophenolate-mofetil. Support for the amendments to claims 11 and 19 may be found throughout the specification, including page 4, lines 15-16 and claim 13 as originally filed. It is respectfully submitted that Uomoto et al. is directed to medicinal compositions containing the cyclic desipeptide PF1022 or an analogue thereto, as active agent. The presently claimed pharmaceutical compositions comprising a solubilized therapeutic agent which is sparingly soluble in water and selected from the group consisting of rapamycin,

tacrolimus and mycophenolate-mofetil are not taught by Uomoto et al. The presently claimed invention is therefore distinguished from the teaching of Uomoto et al., and withdrawal of the rejection of claims 11, 12, 14 and 16-22 under 35 U.S.C.§ 102(e) is therefore respectfully requested.

Claims 11-22 have been rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Akiyama et al. (US 5,576,025) in view of Uomoto et al. (U.S. 5,380,745). Akiyama et al. is relied on for allegedly teaching compositions comprising a polyglycerol fatty acid and/or a lipid and an active agent. The composition can adhere to the digestive tract and remain there for a prolonged period of time, thereby increasing the bioavailability of the active ingredient. The Examiner acknowledges that Akiyama et al. does not disclose the amount of surfactant that may be used in the compositions.

In order to fill the gap of teaching left by Akiyama et al., Uomoto et al. has been cited for allegedly disclosing amounts of surfactants that may be used when delivering poorly soluble drugs. A nonionic surfactant may comprise 5 to 50 parts by weight of the active compound. The Examiner acknowledges that Uomoto et al. does not disclose the drugs rapamycin, tacrolimus or mycophenolate-mofetil, nor the specific polyglycerol fatty acid esters of claim15. Applicant submits that Akiyama et al. also does not teach or suggest the therapeutic agents rapamycin, tacrolimus or mycophenolate-mofetil.

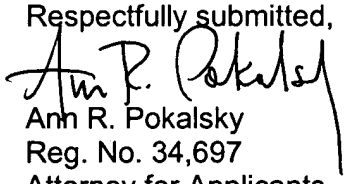
Applicant respectfully submits that the hydrophobic nature of the therapeutic agents presently recited in amended claims 11 and 19, i.e., rapamycin, tacrolimus and mycophenolate-mofetil, presents particular problems with regard to providing pharmaceutically acceptable oral formulations. Only *particular combinations* of excipients are capable of achieving *good bioavailability, high stability and low variability within and between patients*. The formulation according to the present invention is such a formulation. The fact that individual excipients are known for pharmaceutical use does not make their combination obvious since the interaction between individual excipients and their effect on bioavailability of the therapeutic agents, which is critical for the patient, and other properties could not be accurately predicted by one skilled in the art.

It is respectfully submitted that neither Akiyama et al., nor Uomoto et al, taken separately or in combination, discloses or suggests that a combination of a co-surfactant

with an HLB<10, a suitable oil and a surfactant with an HLB>10 would lead to formulations providing adequate oral bioavailability for rapamycin, tacrolimus and mycophenolate-mofetil. Even though the present invention may appear to be simple, Applicant respectfully submits that this is only with the considerable benefit of hindsight reconstruction and *ex-post facto* analysis. Withdrawal of the rejection of claims 11-22 under 35 U.S.C. §103(a) is therefore respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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